



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------------------------------------|-------------|----------------------|---------------------|------------------|
| 10/642,650 | 08/19/2003 | John Brown Thomsen | 010085-027 | 3735 |
| 21839 | 7590 | 04/29/2005 | EXAMINER | |
| BURNS DOANE SWECKER & MATHIS L L P | | | KIM, VICKIE Y | |
| POST OFFICE BOX 1404 | | | ART UNIT | |
| ALEXANDRIA, VA 22313-1404 | | | PAPER NUMBER | |
| | | | 1618 | |
| DATE MAILED: 04/29/2005 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/642,650

Applicant(s)

THOMSEN ET AL.

Examiner

Vickie Kim

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8,37 and 38 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-8,37 and 38 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Status of Application

1. Acknowledgement is made of amendment filed 12/30/2004. The claims 1-8, 37-38 are amended and pending and presented for the examination.

Claim Rejections - 35 USC § 112,2nd

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 5 and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a. Claim 5 recites the limitation "the active sting or bite curing ingredient" in

2. There is insufficient antecedent basis for this limitation in the claim.

It is noted that the limitation has been deleted in instant amendment.

- b. Claim 37 recites "selected from " twice to define the alkanol in lines 3 and

5. Therefore, the said duplicated terms renders the claim indefinite. One of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear what the metes and bounds of the claim is.

Response to Arguments

3. Applicant's arguments filed 12/30/04 have been fully considered but they are not persuasive. However, applicant's arguments with respect to original claims(before this instant amendment) have been considered but are moot in view of the new ground(s) of rejection due to the changes made in scope of the instant claims.

Blackman(US5013545)

Applicant argues that Blackman(US'545, hereinafter) does not teach alcohol(i.e.alkanols such as ethanol, propanol) as an active agent. Applicant's allegation is not correct because US'545 clearly teaches that without the incorporation of any sperate topical active pharmaceutical agent, the alcohol gel of patented composition provides satisfactory antiseptic and bacterial effect for treatment of minor abrasions, lacerations, burns and other skin conditions, see abstract and col. 5, lines 60-65.

Thus, applicant's argument is not persuasive.

Double Patenting Rejection

Appliquant's argument is not persuasive because the subject matter of US'605(patent) drawn to a method of treating infected skin by topical application of gel composition comprising more than 90% C1-4 alkanol or the mixture thereof as an active agent. In light of specification, the said treatment of infected skin encompasses swelling, itching and pain, see column 1, lines 42-45. Thus, the reduction of said symptoms of infected skin should be included in the scope of the patented treatment. Thus, the rejection is maintained. see detailed rejection below.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1618

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Moore et al(US 2054989).

The claims are drawn to a method of treating skin disorders(e.g. pain, swelling, edema, itching) using a composition comprising more than 90 % by weight of an alkanol(s), less than 10% by weight water.

Moore et al(US'989, hereinafter) teach a medicinary and cosmetic alcogel comprising alkanol(s)(e.g. ethanol, propanol, isopropanol, or mixture thereof(see page 3, 1st col. lines 12-18 and examples 2-5), a water less than 10%. Especially, example 2 composition (at page 2) is used as an alcohol massage to make skin feeling cool and skin refreshing preparation, see also col 1, lines 45-49 at page 1.

Applicants claims are different from US'989 because they require specific skin conditions such as pain, swelling, itching or edema.

However, it would have been envisioned by one of ordinary skill in the art at that time of the invention was made that Moore's alcogel(=alcohol gel) is effective massaging aid for alleviating and reducing pains and/or cooling swelling, itching sensation or swelling because rubbing alcohol(over the counter available drug) is available for decades and well known in the art** as an aid for muscle pain, swelling or supplemental aid for massaging therapy, see PTO-892 for extrinsic evidentiary supporting documents.

** (i) definition of rubbing alcohol, on-line medical dictionary.

(ii) definition of massage(by state regumation of the practice of medicine)

Therefore, the claimed invention is readily apparent to any skilled artisan wherein one would have been envisaged to use alcogel for same purpose or obvious to use as a massaging aid to aim the same outcome when Moore's is taken in view of said documents available in the field, and thus obvious absent evidence to the contrary.

As to the limitations recited in the dependent claims(i.e. the time period retained in the skin, for example, 1 minute- 48 hours, 5 minutes- 6 hours) are inherently met because the composition taught by the cited reference and the instant claims is substantially same and thus, one would have envisaged substantially same therapeutic efficacy including the time retained in the skin after topical application. Otherwise, it would have been obvious that the gelled composition must be retained in the skin enough time so that the time allows the drug be absorbed thru the skin layer by preventing quick evaporation as recognized and evidenced by the disclosure of US'545 patent(see background of the patented invention, column 1) and this obvious, absent evidence to the contrary.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 4-7 and 37-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moore et al(US 2054989) in view of Blackman et al(US 5013545) .

Art Unit: 1618

The claims are drawn to a method of treating skin disorders(e.g. pain, swelling, edema, itching) using a composition comprising more than 90 % by weight of an alkanol(s), a polymeric gelling agent and a water less than 10% by weight .

The claims 37-38 require additionally reduction of skin infection of abrasions and gelling agent(0.1-10%).

As mentioned earlier in 102 rejection, Moore et al(US'989, hereinafter) teach a medicinary and cosmetic alcogel comprising alkanol(s)(e.g. ethanol, propanol, isopropanol, or mixture thereof(see page 3, 1st col. lines 12-18 and examples 2-5), a gelling agent such as B fructose diacetone sulfonic acid(= gel former, about 3% by weight, see page 1, 2nd col. Lines 2-10 and 41-42), a water less than 10%.

Especially, example 2 composition (at page 2) is used as an alcohol massage to make skin feeling cool and skin refreshing preparation, col 1, lines 45-49 at page 1.

Applicants claims differ because they require polymeric gelling agent.

Blackman et al(US'545, hereafter) teach an aqueous gel composition comprising ethanol(about 60-90%, see 2, lines 35-43) as an active agent, water(about 0.5-30%) and a polymeric gelling agent such as carboxyvinyl polymers or polyacrylamidomethylpropane sulfonic acid(about 0.5-5%, col.3, lines 10-62) for treating skin conditions caused by insect bite, infections of minor abrasion, see abstract and column 4, lines 50-54.

US'545 teaches that an alcohol gel composition of the patent is effectively used alone for treating skin conditions such as infection of minor abrasions, lacerations, burns, see column 5, line 45-57.

Art Unit: 1618

Thus, the element found to be deficient in Moore's patent(US'989) is remedied when US'989 is taken in view of Blackman(US545) because both patent relates to an alcohol gel for treating and benefiting skin conditions.

As to the limitations recited in the preamble(i.e. the time period retained in the skin, for example, 1 minute- 48 hours, 5 minutes- 6 hours) are inherently met and also taught by the cited reference(US'545, see column 5, lines 1-12 and) and the instant claims is substantially same and thus, one would have envisaged substantially same therapeutic efficacy including the time retained in the skin after topical application. Otherwise, it would have been obvious that the gelled composition must be retained in the skin enough time so that the time allows the drug be absorbed thru the skin layer by preventing quick evaporation as recognized and evidenced by the disclosure of US'545 patent(see background of the patented invention, column 1) and this obvious, absent evidence to the contrary.

One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities, and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

Art Unit: 1618

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-8 and 37-38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13-15 of U.S. Patent No. 5981605. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter of US'605 (patent) drawn to a method of treating infected skin by topical application of gel composition comprising more than 90% C1-4 alkanol or the mixture thereof as an active agent. In light of specification, the said treatment of infected skin encompasses swelling, itching and pain, see column 1, lines 42-45. Thus, the reduction of said symptoms of infected skin should be included in the scope of the patented treatment. Furthermore, since alcohols (e.g. rubbing alcohols) has been known for long time as antiitching or antiseptic against insect bite or sting, one would have been easily modified US'605 teaching to incorporate the method for treating skin disorders caused by insect bite or sting to get maximum benefit because alcohols are easily accessible. In addition to that, conveniences and low manufacturing cost would maximize user's benefits and thus, such modification could be carried out with reasonable expectation of success and with great demand. The scope of the instant claims are embraced by the patented claims and are not considered to be patentably distinct over the patented claims.

Thus, all the claims are properly maintained as rejected.

Conclusion

2. No claim is allowed.
3. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 571-272-0579. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Low be reached on 571-272-0953. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

Art Unit: 1618

published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

**VICKIE KIM
PRIMARY EXAMINER**

Vickie Kim
Primary Patent Examiner
April 28, 2005
Art unit 1618